UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,300	07/31/2001	Gordon E. King	210121.547	3873

500 7590 09/03/2002

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER	
LY, CHEYNE D	

ART UNIT	PAPER NUMBER
1631	8

DATE MAILED: 09/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/920,300	Applicant(s) KING ET AL.	
	Examiner Cheyne D Ly	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The art unit designated for this application has changed. Applicants(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Election/Restrictions

The inventions are distinct, each from the other because of the following reasons:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3, 4 and 8 drawn to an isolated polynucleotide in class 514, subclass 44, an expression vector in class 435, subclass 320.1 and a host cell in class 435, subclass 325. If this Group is elected, then the below summarized sequence election is required.

II. Claim 2 and 7, drawn to an isolated polypeptide and fusion protein in classes 530 and 435, subclasses 350 and 69.7, respectively. If this Group is elected, then the below summarized sequence election is required.

III. Claims 5, drawn to an isolated antibody, or antigen-binding fragment thereof in class 424, subclasses 130.1. If this Group is elected, then the below summarized sequence election is required.

IV. Claim 6 and 16, drawn to a method for detecting the presence of a cancer in a patient by contacting a biological sample with a binding agent and a diagnostic kit in class 436, subclass 64. If this Group is elected, then the below summarized sequence election is required.

V. Claim 9, drawn to a method for stimulating and/or expanding T cells specific for a tumor protein in class 424, subclass 154.1. If this Group is elected, then the

below summarized sequence election is required. Also, if this Group is elected then the below summarized specie election is required.

VI. Claim 10, drawn to an isolated T cell population in class 424, subclass 154.1. If this Group is elected, then the below summarized sequence election is required. Also, if this Group is elected then the below summarized specie election is required.

VII. Claim 11, drawn to a composition comprising of a polypeptide sequence in class 530, subclass 350, polynucleotide sequence in class 435, subclass 6, antibodies in class 424, subclasses 130.1, a fusion protein in class 435, subclass 69.7, a T cell population in class 424, subclass 154.1, and antigen presenting cells in class 424, subclass 130.1. If this Group is elected, then the below summarized sequence election is required. Also, if this Group is elected then the below summarized specie election is required.

VIII. Claims 12 and 13, drawn to a method for stimulating an immune response in a patient and for the treatment of ovarian cancer in a patient by administering a composition in classes 424 and 514, subclasses 154.1 and 2, respectively. If this Group is elected, then the below summarized sequence election is required. Also, if this Group is elected then the below summarized specie election is required.

IX. Claims 14 and 15, drawn to a method for detecting the presence of a cancer in a patient by contacting a biological sample with an oligonucleotide that hybridizes to the oligonucleotide and a diagnostic kit containing said oligonucleotide in class

424 and subclass 64. If this Group is elected, then the below summarized sequence election is required.

X. Claim 17, drawn to a method for the treatment of ovarian cancer in a patient by incubating $CD4^+$ and/or $CD8^+$ T cells isolated from a patient with at least one select component in class 514, subclasses 2 and 44. If this Group is elected, then the below summarized sequence election is required. Also, if this Group is elected then the below summarized specie election is required.

Sequence Election Requirement Applicable to All Groups:

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group draw to amino acid/polypeptide sequence, the Applicants must further elect a single amino acid/polypeptide sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic sequence (See MPEP § 803.04). It is noted that the multiple of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic sequences effectively impossible to reasonably implement.

MPEP § 803.04 states:

Nucleotides sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR

1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction and not a specie election requirement.

SPECIE ELECTION REQUIREMENT FOR GROUPS V, VI and X:

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A: a component, which is a polypeptide

Specie B: a component, which is a polynucleotide

Specie C: a component, which is an antigen presenting cell.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Groups V, VI and X are generic. The species are distinct due to the distinct usages of polynucleotide, polypeptide, or antigen presenting cells for detecting the presence of ovarian cancer in patients. Individually, these distinct species are used in various methods to independently diagnose for the present factors specific to ovarian cancer. For example, oligonucleotides are used to contact sequences contained in biological sample to determine for the presence nucleotide sequences of genes that are implicated in ovarian cancer. Polypeptides are used to contact proteins contained in biological sample to determine for the presence of ovarian cancer proteins. The presence of antigen presenting cells specific for ovarian cancer factors is used in diagnostic methods to detect for ovarian cancer.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

SPECIE ELECTION REQUIREMENT FOR GROUP VII and VIII:

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A: a second component, which is a polypeptide

Specie B: a second component, which is a polynucleotide

Specie C: a second component, which is an antibody

Specie D: a second component, which is a fusion protein

Specie E: a second component, which is a T cell population

Specie F: a second component, which is an antigen presenting cell.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Groups VII and VIII are generic. The species are distinct due to the distinct usages of a polynucleotide, a polypeptide, an antibody, a fusion protein, a T cell population, or an antigen presenting cells for detecting the presence of ovarian cancer in patients. Individually, these distinct species are used in various methods for the detection and treatments of ovarian cancer. For example, oligonucleotides are used to contact sequences contained in biological sample to determine for the presence nucleotide sequences of genes that are implicated in ovarian cancer. Polypeptides are used to contact proteins contained in biological sample to determine for the presence of ovarian cancer proteins. Antibodies specific to ovarian cancer polypeptides are used in various methods for the detection and treatments of ovarian cancer. Fusion proteins are used in a method to stimulate the immune response as a form of treatment for ovarian cancer. The presence of T cells or antigen presenting cells specific for ovarian cancer factors is individually used in methods to for the detection and treatments of ovarian cancer.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions of Groups [I, V (polynucleotide specie), VI (polynucleotide specie), VII (polynucleotide specie), VIII (polynucleotide specie), IX (polynucleotide specie), X (polynucleotide specie)]; [II, IV, V (polypeptide specie), VI (polypeptide specie), VII (polypeptide specie), VIII (polypeptide specie), X (polypeptide specie)]; [III, VII (antibody), VIII (antibody)]; and [VI, VII (T cell), VIII (T cell)] are distinct inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups I, V (polynucleotide specie), VI (polynucleotide specie), VII (polynucleotide specie), VIII (polynucleotide specie), IX (polynucleotide specie), and X (polynucleotide specie), the critical feature is a nucleic acid molecule. For Groups II, IV, V (polypeptide specie), VI (polypeptide specie), VII (polypeptide specie), VIII (polypeptide specie), and X (polypeptide specie), the critical feature is a polypeptide molecule. For Groups III, VII (antibody), and VIII (antibody), the critical feature is an antibody. For Groups VI, VII (T cell), and VIII (T cell), the critical feature is a T cell population. Further, it is acknowledged that various processing steps may cause a peptide of Groups II, IV, V (polypeptide specie), VI (polypeptide specie), VII (polypeptide specie), VIII (polypeptide specie), and X (polypeptide specie) to be directed as to

its synthesis by a polynucleotide set forth in Group I, however, the completely separate chemical and entity types of the inventions of the polynucleotide and poplypeptide support the undue search burden if they were examined together. Additionally, polynucleotide, poplypeptide, antibodies and T cells have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being search separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the four Groupings: [I, V (polynucleotide), VI (polynucleotide specie), VII (polynucleotide specie), VIII (polynucleotide specie), IX (polynucleotide specie), X (polynucleotide specie)]; [II, IV, V (polypeptide specie), VI (polypeptide specie), VII (polypeptide specie), VIII (polypeptide specie), X (polypeptide specie)]; [III, VII (antibody), VIII (antibody)]; and [VI, VII (T cell), VIII (T cell)] are independent and/or distinct invention types for restriction purposes.

Inventions in Groups I, V (polynucleotide specie), VI (polynucleotide specie), VII (polynucleotide specie), VIII (polynucleotide specie), IX (polynucleotide specie), and X (polynucleotide specie) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case of methods for ovarian therapy and diagnosis, a polynucleotide of Group I may be utilized in the distinct usages as in the method of Group V (polynucleotide

specie), which is a method for stimulating and/or expanding T cells specific for a tumor protein. As in Group VI (polynucleotide specie), which is an isolated T cell population. As in Group VII (polynucleotide specie), which is a composition used for treating or detecting ovarian cancer. As needed in Group VIII (polynucleotide specie), which is a method for stimulating an immune response in a patient and the treatment of ovarian cancer by administering a composition. As needed in Group IX (polynucleotide specie), which is a method for a detecting the presence of a cancer in a patient by contacting a biological sample with an oligonucleotide that hybridizes to the oligonucleotide. As needed in Group X, which is a method for the treatment of ovarian cancer by incubating $CD4^+$ and/or $CD8^+$ T cells isolated from a patient with at least one select component. Alternately, a polynucleotide may be utilized as an antisense oligonucleotide for RNA interference studies, for example. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

Inventions in Groups II, IV, V (polypeptide specie), VI (polypeptide specie), VII (polypeptide specie), VIII (polypeptide specie), and X (polypeptide specie) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case of methods for ovarian therapy and diagnosis, a polypeptide of Group II may be utilized in the distinct usages as need in the method of Group IV for detecting the presence of a cancer in a patient by contacting a

biological sample with a binding agent. As needed in Group V (polypeptide specie), which is a method for stimulating and/or expanding T cells specific for a tumor protein. As in Group VI, which is an isolated T cell population. As in Group VII (polypeptide specie), which is a composition used for treating or detecting ovarian cancer. As needed in Group VIII (polypeptide specie), which is a method for stimulating an immune response in a patient and the treatment of ovarian cancer by administering a composition. As needed in Group X, which is a method for the treatment of ovarian cancer by incubating $CD4^+$ and/or $CD8^+$ T cells isolated from a patient with at least one select component. Alternately, a polypeptide may be utilized in binding assays to determine unknown ovarian cancer proteins, for example. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

Inventions in III, VII (antibody) and VIII (antibody) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case of methods for ovarian therapy and diagnosis, an antibody of Group III may be utilized in the distinct usages as in Group VII (antibody), which is a composition used for treating or detecting ovarian cancer. As needed in Group VIII (antibody), which is a method for stimulating an immune response in a patient and the treatment of ovarian cancer by administering a composition. Alternatively, antibodies specific to ovarian cancer polypeptides may be used to characterize unknown proteins interacting

with ovarian cancer proteins or immunocytochemical staining for morphological studies, for example. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

Inventions in VI, VII (T cell), and VIII (T cell) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case of methods for ovarian therapy and diagnosis, a T cell population of Group VI may be utilized in the distinct usages as in Group VII (T cells), which is a composition used for treating or detecting ovarian cancer. As needed in Group VIII (T cells), which is a method for stimulating an immune response in a patient and the treatment of ovarian cancer by administering a composition. Alternatively, ovarian cancer specific T cells may be used in Chromium-51 release assay for characterizing tumor cytolysis, for example. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement e traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 193), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
August 27, 2002

ARDIN H. MARSCHEL
PRIMARY EXAMINER